UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 19-2130 (L)
(8:18-cv-00883-PWG)

In re: CIGAR ASSOCIATION OF AMERICA; CIGAR RIGHTS OF AMERICA; PREMIUM CIGAR ASSOCIATION, f/k/a International Premium Cigar and Pipe Retailers Association

Appellants

AMERICAN ACADEMY OF PEDIATRICS; MARYLAND CHAPTER-AMERICAN ACADEMY OF PEDIATRICS; AMERICAN CANCER SOCIETY CANCER ACTION NETWORK; AMERICAN HEART ASSOCIATION; AMERICAN LUNG ASSOCIATION; CAMPAIGN FOR TOBACCO-FREE KIDS; TRUTH INITIATIVE; DR. LEAH BRASCH, MD; DR. CYNTHIA FISHMAN, MD; DR. LINDA GOLDSTEIN, MD; DR. STEVEN HIRSCH, MD; DR. DAVID MYLES, MD

Plaintiffs – Appellees

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION; NORMAN E. SHARPLESS, in his official capacity as Acting Commissioner of Food and Drugs; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR, II, in his Official capacity as Secretary of Health and Human Services

Defendants

No. 19-2132
(8:18-cv-00883-PWG)

AMERICAN ACADEMY OF PEDIATRICS; MARYLAND CHAPTER-AMERICAN ACADEMY OF PEDIATRICS; AMERICAN CANCER SOCIETY CANCER ACTION NETWORK; AMERICAN HEART ASSOCIATION; AMERICAN LUNG ASSOCIATION; CAMPAIGN FOR TOBACCO-FREE KIDS; TRUTH INITIATIVE; DR. LEAH BRASCH, MD; DR. CYNTHIA FISHMAN, MD; DR. LINDA GOLDSTEIN, MD; DR. STEVEN HIRSCH, MD; DR. DAVID MYLES, MD

Plaintiffs – Appellees

v.

AMERICAN E-LIQUID MANUFACTURING STANDARDS ASSOCIATION; AMERICAN VAPING ASSOCIATION; SMOKE-FREE ALTERNATIVES TRADE ASSOCIATION- CALIFORNIA; ARIZONA SMOKE FREE BUSINESS ALLIANCE; SMOKE-FREE ALTERNATIVES TRADE ASSOCIATION- CONNECTICUT; INDIANA SMOKE FREE ASSOCIATION; SMOKE-FREE ALTERNATIVES TRADE ASSOCIATION- HAWAII; IOWANS FOR ALTERNATIVE TO SMOKING AND TOBACCO; SMOKE-FREE ALTERNATIVES TRADE ASSOCIATION- LOUISIANA; KENTUCKY SMOKE FREE ASSOCIATION; SMOKE-FREE ALTERNATIVES TRADE ASSOCIATION- RHODE ISLAND; MARYLAND VAPOR ALLIANCE; SMOKE-FREE ALTERNATIVES TRADE ASSOCIATION- TEXAS; NEW YORK STATE VAPOR ASSOCIATION; SMOKE-FREE ALTERNATIVES TRADE ASSOCIATION- WISCONSIN; OHIO VAPOR TRADE ASSOCIATION; RIGHT TO BE SMOKE-FREE COALITION; SMOKE FREE ALTERNATIVES TRADE ASSOCIATION; TENNESSEE SMOKE FREE ASSOCIATION; TEXAS VAPOR COALITION

Intervenors – Appellants

and

UNITED STATES FOOD AND DRUG ADMINISTRATION; NORMAN E. SHARPLESS, in his official capacity as Acting Commissioner of Food and Drugs; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR, II, in his Official capacity as Secretary of Health and Human Services

Defendants

No. 19-2198
(8:18-cv-00883-PWG)

AMERICAN ACADEMY OF PEDIATRICS; AMERICAN CANCER SOCIETY CANCER ACTION NETWORK; AMERICAN HEART ASSOCIATION; AMERICAN LUNG ASSOCIATION; LEAH BRASCH, MD; CAMPAIGN FOR TOBACCO-FREE KIDS; CYNTHIA FISHMAN, MD; LINDA GOLDSTEIN, MD; STEVEN HIRSCH, MD; DAVID MYLES, MD; TRUTH INITIATIVE; MARYLAND CHAPTER- AMERICAN ACADEMY OF PEDIATRICS

Plaintiffs – Appellees

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION; NORMAN E. SHARPLESS, in his official capacity as Commissioner of Food and Drugs; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR, II, in his Official capacity as Secretary of Health and Human Services

Defendants - Appellants

No. 19-2242
(8:18-cv-00883-PWG)

In re: AMERICAN E-LIQUID MANUFACTURING STANDARDS ASSOCIATION; AMERICAN VAPING ASSOCIATION; ARIZONA SMOKE

FREE BUSINESS ALLIANCE; INDIANA SMOKE FREE ASSOCIATION; IOWANS FOR ALTERNATIVE TO SMOKING AND TOBACCO; KENTUCKY SMOKE FREE ASSOCIATION; MARYLAND VAPOR ALLIANCE; NEW YORK STATE VAPOR ASSOCIATION; OHIO VAPOR TRADE ASSOCIATION; RIGHT TO BE SMOKE-FREE COALITION; SMOKE FREE ALTERNATIVES TRADE ASSOCIATION; SMOKE-FREE ALTERNATIVES TRADE ASSOCIATION- CALIFORNIA; SMOKE-FREE ALTERNATIVES TRADE ASSOCIATION- CONNECTICUT; SMOKE-FREE ALTERNATIVES TRADE ASSOCIATION- HAWAII; SMOKE-FREE ALTERNATIVES TRADE ASSOCIATION- LOUISIANA; SMOKE-FREE ALTERNATIVES TRADE ASSOCIATION- RHODE ISLAND; SMOKE-FREE ALTERNATIVES TRADE ASSOCIATION- TEXAS; SMOKE-FREE ALTERNATIVES TRADE ASSOCIATION- WISCONSIN; TENNESSEE SMOKE FREE ASSOCIATION; TEXAS VAPOR COALITION

Appellants

AMERICAN ACADEMY OF PEDIATRICS; AMERICAN CANCER SOCIETY CANCER ACTION NETWORK; AMERICAN HEART ASSOCIATION; AMERICAN LUNG ASSOCIATION; LEAH BRASCH; CAMPAIGN FOR TOBACCO-FREE KIDS; CYNTHIA FISHMAN; LINDA GOLDSTEIN; STEVEN HIRSCH; DAVID MYLES; MARYLAND CHAPTER- AMERICAN ACADEMY OF PEDIATRICS; TRUTH INITIATIVE

Plaintiffs – Appellees

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION; SCOTT GOTTLIEB, in his Official capacity as Commissioner of Food and Drugs; NORMAN E. SHARPLESS, in his Official capacity as Commissioner of Food and Drugs; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR, II, in his Official capacity as Secretary of Health and Human Services; AMERICAN ASSOCIATION FOR RESPIRATORY CARE

Defendants

On Appeal from the United States District Court for the District of Maryland

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INTERVENORS-APPELLANTS' REPLY IN SUPPORT OF MOTION TO STAY PENDING APPEAL AND TO EXPEDITE CONSIDERATION ON THE MERITS

Respectfully submitted,

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Intervenors-Appellants vapor associations respectfully submit this reply in support of their Motion to Stay Pending Appeal and to Expedite Consideration on the Merits. We note the Food and Drug Administration and other government Defendants ("FDA") have "no objection" to expedition (Doc. 46 at 2) and that Plaintiffs-Appellees ("Plaintiffs") did not address the request to expedite or otherwise oppose such relief. As to the stay motion, neither FDA's nor Plaintiffs' response demonstrates that a stay should be denied in this case.

I. FDA's Newly Issued PMTA Deadline Is Unlawful And Highlights The Need For A Temporary Stay

We begin, however, by responding to FDA's 28(j) letter submitted on January 2, 2020. Doc. 50. FDA provided notice that it had issued final guidance setting the same PMTA deadline established by the district court in the Remedies Order (*i.e.*, May 12, 2020). FDA argues that the guidance confirms the vapor associations' motion to stay should be denied and that it "may well moot the intervenors' appeal in this case." *Id.* at 2. Neither statement has any merit.

The district court held in the Merits Decision that a PMTA filing deadline applying to all vapor products, as does the new guidance (Doc. 50 at 1), constitutes a legislative rule that is subject to Administrative Procedure Act ("APA") notice-and-comment rulemaking. Ex. A at 47-53.[1] Thus, in issuing this guidance, FDA

[1] "Ex." refers to exhibits attached to the motion. Doc. 36.

once again violated the APA by establishing a deadline without formal notice-and-comment procedures. This deadline is unlawful on its face and appears to be nothing more than an attempted end-around of this appeal.

The guidance, moreover, does not moot this litigation. The vapor associations argue the district court did not have authority or any other grounds to impose its own May 12, 2020 deadline; rather, the court should have remanded for further proceedings with any new cutoff being promulgated through APA notice-and-comment rulemaking. The unlawful guidance, therefore, does not address the relief sought in this appeal. If anything, it shows the need for this Court to enter a stay and clarify the required procedures for establishing PMTA deadlines to protect manufacturers' APA procedural rights.

II. The Vapor Associations Have Established A Likelihood Of Success

While FDA does not address the "likelihood of success" prong (Doc. 46 at 9), Plaintiffs argue that the court had authority to impose its own PMTA deadline. Plaintiffs' response fails on multiple grounds.

First, the cases cited by the district court and Plaintiffs do not support injunctive relief here. Doc. 47 at 13-14; Ex. B at 4-5, 11. As noted in the motion, none of those cases hold that a court, where an agency violated APA notice-and-comment requirements, can award injunctive relief that completely strips the agency of all discretion. Doc. 36-1 n.5. There was simply no occasion for those

courts to consider whether they had authority, under the APA or otherwise, to replace stakeholder rights to notice-and-comment rulemaking. In fact, only one case even involved a failure of notice-and-comment, and that court considered injunctive relief that would have preserved agency discretion on remand, something that the district court did not do when it set the deadline. *Id.* Plaintiffs did not otherwise address case law cited in the motion holding that courts cannot award injunctive relief in such circumstances. Doc. 36-1 at 10-12.

Moreover, the two *Thompson* decisions that the district court and Plaintiffs rely on make this same point. Doc. 47 at 14; Ex. B at 11. When discussing an appropriate remedy where HUD had violated the Fair Housing Act, the *Thompson* court cites the First Circuit's decision in *NAACP v. HUD*, 817 F.2d 149 (1st Cir. 1987). *See also* Ex. B at 11 (district court citing *NAACP*). *Thompson v. United States Dep't of HUD*, 2006 U.S. Dist. LEXIS 9416, at *35 (D. Md. Jan. 10, 2006); *Thompson v. United States HUD*, 348 F. Supp. 2d 398, 464 (D. Md. 2005). In *NAACP*, the court explicitly warned the lower court that it must preserve the agency's discretion on remand when fashioning any injunctive relief. *NAACP*, 817 F.2d at 159 (court must "preserv[e] for the agency its discretionary options"). In

contrast, the district court, despite having found that FDA had discretion to set an across-the-board deadline, left the agency with no discretion to do so.[2]

Second, Plaintiffs complain that, while conceding the Fourth Circuit has never adopted the "extraordinary circumstances" exception, the vapor associations do not cite any decisions questioning that rule. Doc. 47 at 15. Plaintiffs miss the point. As discussed in the motion, no court has applied that exception by making policy judgments, as did the district court here, that should be made by an agency through the exercise of lawful discretion. Doc. 36-1 at 12-13. Rather, courts refuse to apply it where an agency would have discretion to act on remand. *Id.* In fact, we are not aware of a single case that has affirmatively applied the rule to impose injunctive relief under any rationale, and Plaintiffs cite to none.

Third, Plaintiffs set up a strawman when they argue that courts are not subject to APA notice-and-comment procedures. Doc. 47 at 15-16. The vapor associations never made that argument. Rather, the district court held that an across-the-board PMTA deadline constitutes a legislative rule requiring notice-and-comment. Thus, the court was obligated to remand back to FDA.

[2] The district court's clarification order allowing FDA to enforce earlier than May 2020 does not change this. Doc. 46 at 8; D. Md. ECF 132. That order clearly refers to case-by-case enforcement, not an across-the-board deadline. Indeed, the district court expressly rejected a shorter deadline proposed by Plaintiffs.

Fourth, Plaintiffs downplay the district court's finding of APA procedural error. Doc. 47 at 14; Ex. A at 6. This is a curious position given they specifically requested such relief. Compl. at 39-41. Nevertheless, this does nothing to inform this Court as to whether movants are likely to succeed on the merits, but instead illustrates the duplicitous nature of the Plaintiffs' approach. If Plaintiffs have a right to notice-and-comment rulemaking, so do other stakeholders, including manufacturers. The APA ensures *all* interested parties can avail themselves of reasoned agency decision-making. Plaintiffs cannot have it both ways.

Finally, in distancing themselves from their own Complaint, Plaintiffs mischaracterize the district court's ruling. While Plaintiffs highlight the court's holding that the August 2022 cutoff was inconsistent with the TCA, Plaintiffs never mention the court's additional finding that FDA retains some discretion to adopt a new filing deadline consistent with its opinion. Ex. A at 8, 29-30. As such, the procedural-related holding was a key element of the court's Merits Decision. The court initially indicated that the matter would be remanded for further proceedings, including comment by manufacturers. *Id.* at 53-54; D. Md. ECF 84 at 2. Thus, the court did more than just vacate what it viewed as unlawful guidance; it also anticipated giving FDA a chance to correct the procedural error.

III. Vapor Product Manufacturers Will Suffer Irreparable Harm

The parties argue that manufacturers will not suffer irreparable harm if this Court does not issue a decision before May 2020. Their arguments fall short.

First, both FDA and Plaintiffs maintain that manufacturers do not have a right to market vapor products beyond the Deeming Rule's effective date and thus cannot be irreparably harmed. Doc. 46 at 9-10; Doc. 47 at 16-17. Again, the parties misconstrue this appeal. Manufacturers have a right to formal notice-and-comment rulemaking for any across-the-board filing deadline. In fact, these procedural rights were just violated by virtue of FDA's recently issued guidance adopting the court's deadline without formal rulemaking.[3]

Second, the parties argue that a remand for further rulemaking is not certain to provide relief because FDA could decide to enforce the PMTA requirement on a case-by-case basis or select a shorter time period on remand. Doc. 46 at 10-11; Doc. 47 at 17. But where an injury is comprised of a procedural error, such as a failure of notice-and-comment rulemaking, the movant does not "have to prove that if he had received the procedure the substantive result would have been altered. All that is necessary is to show that the procedural step was connected to

[3] It is true that the Merits Decision suggested that FDA would only need to adopt "Guidance" using notice-and-comment. Ex. A at 53. But that directly contradicts the court's APA ruling. An across-the-board deadline cannot, as a matter of law, legitimately be both a legislative rule and an interpretive rule.

the substantive result. . . . If a party claiming the deprivation of a right to notice-and-comment rulemaking under the APA had to show that its comment would have altered the agency's rule, section 553 would be a dead letter." *Sugar Cane Growers Coop. of Fla. v. Veneman*, 289 F.3d 89, 94-95 (D.C. Cir. 2002) (lack of notice-and-comment is an injury-in-fact for purposes of standing).

In any event, it is not speculative as to whether a remand in this case would provide manufacturers with relief. Beginning with the Deeming Rule, FDA has consistently recognized the need for a compliance period to: (i) ensure that manufacturers have adequate time to comply and file high-quality PMTAs; (ii) allow the agency to complete the process of developing "foundational" rules and guidance for manufacturers to follow when completing applications; (iii) avoid a mass exit of products used by adults to move away from more dangerous cigarettes; and (iv) provide FDA with sufficient time to process filed PMTAs. Doc. 36-1 at 3-5. In fact, in balancing these stakeholder interests, FDA has established or proposed deadlines on at least four occasions, with the most recent only last week (albeit in an unlawful manner). *Id.* Indeed, providing an adequate compliance period was a core assumption underlying the Deeming Rule, *id.* at 4, and thus FDA would need to set a new date, this time through a rulemaking.

Third, as to the impact of a shortened deadline on the vapor marketplace, FDA is incorrect when it says that it is the PMTA requirement, not the district

court's order, that would lead to a mass market exit of products. Doc. 46 at 11. Its claim is belied by Director Zeller's own declaration in which he repeatedly links the possibility of a mass exit to a PMTA deadline that is too short, thus placing at risk the health of countless addicted smokers who would migrate back to cigarettes. Ex. F at ¶15. As the district court held, FDA has authority to avoid such an adverse outcome by setting a more reasonable application cutoff.

Fourth, when arguing in conclusory fashion that manufacturers can file PMTAs by the court-imposed deadline, the parties completely ignore sworn testimony presenting numerous reasons why they cannot. Doc. 36-1 at 14-19; Doc. 46 at 12; Doc. 47 at 18. Significantly, the mere "filing" of an application by the cutoff will not alleviate any potential harm; rather, the risk of filing a timely, but incomplete, PMTA that could be immediately rejected is the salient concern. Doc. 36-1 at 18. It is only through formal notice-and-comment rulemaking that FDA would be compelled to consider manufacturer comments and explain why a chosen deadline adequately resolves the remaining uncertainties and sources of delay.

Finally, it is irrelevant that three manufacturers will have filed PMTAs by May 2020. These companies – Reynolds, NJOY, and JUUL – make non-refillable cartridge/pod systems (unlike movants), are valued in the billions of dollars, and do not represent the thousands of small manufacturers and vape shops (many "Mom and Pop" outfits) who make up the trade associations' memberships and

will bear the brunt of the court's deadline. Ex. C at ¶18. It is no surprise that Director Zeller expressed concerns that these small businesses, who have never worked with FDA before, run a risk of filing incomplete PMTAs if not given sufficient time and agency guidance. Ex. F at 13-14.

IV. Plaintiffs Have Not Shown Substantial Harm

The motion to stay does not seek an indefinite hold on the May 2020 deadline; rather, the vapor associations only seek a stay of a few months in the event the Court requires such time to issue an opinion. In that context, the vapor associations pointed out that any information about specific products that could be gleaned from a PMTA will not be available until such applications are approved at year's end at the earliest, and more likely well into 2021 or 2022 – a fact that Plaintiffs do not challenge. Doc. 36-1 at 19-20. Thus, the impact, if any, on Plaintiffs' mission or resources will likely be minimal. FDA did not offer any response showing it would be prejudiced by a temporary stay.[4]

[4] Contrary to Plaintiffs' claims, they would not have obtained any relevant information through the PMTA process regarding the recent outbreak of lung disease involving illicit and black-market THC products. Those products contain illegal drugs and are either not subject to the PMTA requirement because they do not contain tobacco-derived ingredients, *see* 21 U.S.C. §321(rr), or the drug dealers selling them would never risk criminal prosecution by filing a PMTA with FDA.

V. The Interests Of Adult Smokers Justify A Temporary Stay

The vapor associations vehemently oppose underage use and Plaintiffs are wrong that vape shops are responsible for the highest rates of underage sales. Doc. 39 at 20 n.15. FDA's own enforcement data show that, as of October 31, 2019, only 6% percent of such sales were made by vape shops. The vast majority (over 80%) occurred in convenience stores/gas stations/drug stores that do not sell refillable open systems manufactured by the trade associations' members. Doc. 36-1 at 2. This data also show that about 90% of such sales involved non-refillable closed systems (cartridges/pods), like JUUL.[5] In fact, FDA states repeatedly in the recently issued compliance policy that "youth overwhelmingly prefer certain flavors of cartridge-based" vapor products that "are not the products typically produced in vape shops." *E.g.*, Doc. 50 at 21.

Moreover, the parties' claims that the May 2020 deadline will not leave smokers without access to vapor products is directly contradicted by Director Zeller's declaration. Doc. 46 at 15; Doc. 47 at 21-22. He concludes that, even if products come on to the market later – which the motion shows could be years from now – the "sudden and very dramatic reductions in availability" could result in significant public health harm in the interim. Ex. F at 12-13.

[5] FDA Compliance Check Statistics, https://tinyurl.com/ydznamcb.

Finally, FDA's claims that vapor products might not provide addicted smokers with substantial health benefits are contravened not only by governmental organizations like the National Academies of Sciences and Public Health England (both of which have concluded based on extensive reviews of research to date that vaping is far less risky than smoking), D. Md. ECF 37-1 at 2, but also by Director Zeller's declaration and FDA's balancing of adult interests when setting compliance periods, Doc. 36-1 at 3-5. Indeed, there is extensive research demonstrating that vaping helps adults fully transition away from cigarettes. For example, a recent one-year clinical trial published in the *New England Journal of Medicine* found that vaping is nearly twice as effective as other cessation products (*i.e.*, nicotine replacement therapies).[6]

At a minimum, even assuming *arguendo* that additional research is required to confirm those benefits, jeopardizing such potential through the denial of a temporary stay would be unwarranted.

[6] *A Randomized Trial of E-Cigarettes versus Nicotine-Replacement Therapy*, New Eng. J. Med. (Feb. 14, 2019), https://tinyurl.com/ygaqwba4. Two recent surveys of almost 100,000 U.S. vapers also found the vast majority had completely replaced smoking with vaping. D. Md. ECF 37-1 at 3.

January 7, 2020

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on January 7, 2020, I caused to be electronically filed the foregoing with the Clerk of the Court for the U.S. Court of Appeals for the Fourth Circuit using the appellate CM/ECF system. All participants in the case are registered CM/ECF users and will be served by the CM/ECF system.

/s Eric P. Gotting
Eric P. Gotting

CERTIFICATE OF COMPLIANCE

1. This reply complies with the type-volume limitation of Fed. R. App. P. 27(d)(2)(A) because it contains 2,588 words, excluding the parts of the reply exempted by Fed. R. App. P. 27(d)(2) and Fed. R. App. P. 27(a)(2)(B).

2. This reply complies with the type-face requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman 14-point font.

January 7, 2020

/s Eric P. Gotting
Eric P. Gotting